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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,061	06/20/2003	Cesar Z. Lina	P-3460(CON)	5656

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EXAMINER	
HAND, MELANIE JO	
ART UNIT	**PAPER NUMBER**
3761	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,061	LINA ET AL.	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments, see Remarks, filed August 9, 2005 with respect to the objection of Claims 1, 8, 10 and 11 have been fully considered but they are not persuasive. Examiner agrees that it is entirely possible to achieve formation of two varying states from one homogenous solution after said solution has been ejected from a coating or spraying means. However, Applicant's arguments are directed to an embodiment of the foam that is present after an elapsed period of time that is not set forth clearly in the claims. The claims 8 and 11 as written are directed to a porous pad formed when a nontoxic substance is sprayed onto a wound site and the substance foams up to conform to the dimensions of the site. Examiner acknowledges that the process of forming a partial outer surface with smaller average pore size via compression occurring when the foam presses against the walls of a wound site is known in the art and does in fact occur. The amendment of claims 8 and 11 to include reference to this formation of the partial outer surface set forth in claims 1 and 10 would render claims 8 and 11 consistent with Claims 1 and 10.

Applicant's arguments with respect to the rejection(s) of claim(s) 1-7,9,10 and 12-17 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a newly found prior art reference that teaches a foam wound dressing with a porous outer surface and porous inner body, wherein the pores in the outer surface are smaller than the pores in the inner body.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6, 9, 10 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt ('982) in view of McRae et al (U.S. Patent No. 3, 978,855).

With respect to **Claims 1 and 10:** Hunt teaches a porous pad 102 (Fig. 1) that is permeable to liquids and that is held in place by a surgical drape 701 with adhesive providing a seal around said pad and wound (Col. 5, lines 26-29). Hunt also teaches a vacuum canister 100 for collecting drainage fluid that is sucked from the wound via a suction pump 6 and connected to the porous pad through a drainage tube 101 (Fig. 1). Hunt does not teach an outer surface with pores of a first size contacting the wound or a pad with an inner body with pores of a second average size. McRae teaches a wound dressing comprised of open-celled polyurethane foam (Col. 4, lines 53-58) McRae teaches that the polyurethane dressing is compressed to cause cells near at least one surface of said foam to collapse either temporarily or permanently, decreasing their pore size and thus creating a microporous skin on at least that particular surface area, leaving the cells in areas remote from said skin at their original size (now larger compared to the pores at the skin surface). McRae teaches that said first and second pore sizes are to promote sufficient wicking and absorption at the microporous skin surface that is adjacent the wound surface and the larger size is to allow ready absorption while still being small enough to be capable of prohibiting excess exudate absorbed by the microporous skin to pass into the remote region. Therefore it would be obvious to one of ordinary skill in the art to modify the dressing of Hunt by compressing said dressing so

as to collapse some of the pores at a surface to a first size to create a microporous skin and keep the remote pores at a second larger pore size as taught by McRae.

With respect to **Claim 2:** Hunt teaches that a hole is cut through all layers of the surgical drape 701 holding the dressing in place to accommodate the drainage tube (Col. 5, lines 30-33).

With respect to **Claim 3:** By virtue of having pores in a dressing that are capable of being drained of exudates via negative pressure from a suction pump, the pores of a second average size in the dressing of the combined teaching of Hunt and McRae are considered herein to be vacuum-compatible.

With respect to **Claim 4:** Hunt teaches that the dressing is a pad of polyurethane foam (Col. 5, lines 49-51).

With respect to **Claim 5:** McRae teaches that pores in the microporous skin area have a diameter in the range of 0.2-200 microns and the pore size in the region remote from said microporous skin is at least 200 microns. (Col. 4, lines 42-45, 52-57)

With respect to **Claim 6:** Hunt teaches that the surgical drape is comprised of polyurethane film (Col. 8, lines 27-28).

With respect to **Claim 9:** McRae teaches a wetting agent that an open-celled polyurethane foam is inserted into to a desired amount to achieve a particular pore size. (Col. 6, lines 28-42)

With respect to **Claims 12 and 13:** McRae teaches that said microporous skin is formed from the original foam material by compression and not by the addition of another structural entity or chemical compound, therefore the dressing of the combined teaching of Hunt and McRae is a unitary assembly.

With respect to **Claims 14 and 15:** Hunt teaches that the seal around the wound site is substantially airtight (Col. 6, line 18).

With respect to **Claim 16:** Hunt teaches one filter interposed between a suction pump and a vacuum canister (Col. 6, lines 57-59).

With respect to **Claim 17:** Hunt teaches that a suction pump is adapted to draw liquid from a sealed porous pad through a drainage conduit and into a vacuum canister (Col. 6, lines 23-25).

Claims 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt et al (U.S. Patent No. 6,142,982) in view of McRae et al ('855) as applied to claims 1-6, 9, 10 and 12-17 above, and further in view of Shioya et al (U.S. Patent No. 4,997,425).

With respect to **Claim 7:** The combined teaching of Hunt and McRae does not teach the addition of an antimicrobial agent to said wound dressing. Shioya teaches the addition of an antimicrobial agent to the porous wound dressing (Col. 6, line 65-Col. 7, line 2). The benefits of an antimicrobial agent are well known and applicable to devices contacting a wound surface, therefore it would be obvious to someone of ordinary skill in the art to

modify the dressing of the combined teaching of Hunt and McRae by adding an antimicrobial agent as taught by Shioya.

Claims 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt et al (U.S. Patent No. 6,142,982) in view of McRae et al ('855) as applied to claims 1-7, 9, 10 and 12-17 above, and further in view of Coffee (U.S. Patent No. 6,252,129)

With respect to **Claims 8 and 11:** The combined teaching of Hunt and McRae does not teach a foam dressing that may be released from a spray nozzle and deposited directly into the wound cavity, subsequently conforming to the shape of the wound cavity. Coffee teaches spraying a nontoxic polymeric flexible foam deposit into a wound to form a cavity wound dressing, with the dressing conforming to the contours of a cavity wound (Col. 13, lines 52-55). It would be obvious to further modify the wound dressing of the combined teaching of Hunt and McRae to be able to be sprayed directly onto the wound wherein the dressing is a foam material that conforms to the shape of the wound as these spray devices are known, as taught by Coffee (Col. 1, lines 14-17).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER